US-PAT-NO: 5501857

DOCUMENT-IDENTIFIER: US 5501857 A

TITLE: Oral nutritional and dietary composition

---------- KWIC ---------

Detailed Description Text - DETX (5):
In one embodiment, the invention provides a nutritional composition whose components are incompatible, and which incompatible components are physically separated from each other until they reach their in vivo situs. The composition includes two components. One of the components is cultures of viable microorganisms, e.g., bacteria or fungi or live cell yeasts, or combinations thereof. By live cell yeasts is meant, a yeast culture containing live yeast cells but not containing yeast metabolites and/or the yeast growth media. The other of the components is nutritional supplements, e.g., vitamins and/or minerals. Each component necessary to make and use the present invention is commercially available or can be synthesized using known methodologies. The two components are separated from one another. One of the components is enclosed in the inner capsule. The outer capsule contains the inner capsule and the other component. In a preferred embodiment, the microbial cultures are enclosed in a first capsule which is then enclosed with the vitamin and/or mineral supplements in a second such capsule, i.e., a "capsule-in-a-capsule" structure. However the invention also comprehends the reversal of the components, i.e., the vitamins and/or mineral supplements are enclosed in a first capsule which is then enclosed with the microorganisms in a second capsule. The microorganisms of the one component serve the valuable function of repopulating the rumen and/or intestines, thus enabling digestion to resume, producing digestive enzymes, and correcting acid imbalances which result from rumen or intestinal microbial microorganism depopulation.

Detailed Description Text - DETX (74):
The outer capsule contains the inner capsule and the vitamin and/or mineral admixture. Each capsule-in-a-capsule contains 5 g of live cell

Saccharomyces
cerevisiae culture (including standard formulation overages), and 6 g of
vitamin and mineral admixture. The vitamin and mineral admixture contains the
following amounts per capsule as indicated in parentheses: vitamin A
(2.8.times.10.sup.5 IU), vitamin D.sub.3 (4.2.times.10.sup.4 IU), vitamin E
(425 IU), vitamin B12 (1,110 mcg), niacin (1,715 mg), pantothenic acid (8.5
mg), choline (425 mg), biotin (43 mcg), cobalt (1.7 mg), copper (8.5 mg), iron
(17 mg) , manganese (17 mg) , zinc (43 mg) and trace quantities of riboflavin,
thiamine, folic acid, vitamin K, vitamin C and selenium. The vitamin and
mineral admixture is preferably combined with kelp, an acceptable and
nutrient-rich feed grade carrier.

Detailed Description Text - DETX (80):
The outer capsule contains the inner capsule and the vitamin and/or mineral
admixture. Each capsule-in-a-capsule contains 5 g of Saccharomyces cerevisiae
live cell culture and 0.25 g of lactic acid bacterial cultures (including
standard formulation overages), and 6 g of vitamin and mineral admixture. The
vitamin and mineral admixture is preferably combined with kelp, an acceptable
and nutrient-rich feed grade carrier. The vitamins, minerals and kelp are in
the outer capsule.

Detailed Description Text - DETX (120):
Capsule-in-a-capsule vehicles appropriate for administration to adult cattle
are prepared by the method as described hereinbefore. The inner capsule
contains the vitamin and/or mineral admixture, and the outer capsule contains
the inner capsule and probiotic microbial culture of live cell Saccharomyces
cerevisiae.

Detailed Description Text - DETX (127):
Capsule-in-a-capsule vehicles appropriate for administration to adult cattle
are prepared by the method as described hereinbefore. The inner capsule
contains the vitamin and/or mineral admixture, and the outer capsule contains
the inner capsule and probiotic microbial culture of Propionibacterium
freudenreicheii, live cell Saccharomyces cerevisiae, and Aspergillus

oryzae.

Detailed Description Text - DETX (134):
Capsule-in-a-capsule vehicles appropriate for administration to adult cattle are prepared by the method as described hereinbefore. In this embodiment, as in Example 16, the vitamin and/or mineral admixture is in the inner capsule. In this Example, the outer capsule contains the inner capsule and probiotic microbial culture of Propionibacterium freudenreicheii, live cell Saccharomyces cerevisiae, and Aspergillus oryzae, and Lactobacillus acidophilus, Lactobacillus lactis, Lactobacillus casei, Streptococcus faecium and Pediococcus cerevisiae.

Detailed Description Text - DETX (139):
Capsule-in-a-capsule vehicles appropriate for administration to incoming feedlot cattle and adult cattle suffering from rumen acidosis are prepared by the method as described hereinbefore. In this embodiment, the vitamin and/or mineral admixture is contained in the inner capsule. The outer capsule contains the inner capsule and probiotic microbial culture of Propionibacterium species, live cell Saccharomyces cerevisiae, and Aspergillus oryzae.

Detailed Description Text - DETX (172):
Capsule-in-a-capsule vehicles appropriate for administration to livestock or ratites are prepared by the method described hereinbefore. In this Example, the probiotic is in the inner capsule, and the outer capsule contains the inner capsule and the vitamin and/or mineral admixture. The vitamin and/or mineral admixture is formulated to the specific animal, its age and for the specific dietary purpose. The probiotic is selected from the list of non-spore forms and/or live cell culture forms of Direct-Fed Microorganisms reviewed by the Food and Drug Administration Center for Veterinary Medicine. By nonspore forms is meant that the probiotic culture does not exist solely in the spore form. Where yeast is selected as a probiotic, only a live cell yeast culture is used. The probiotic culture is present in a quantity at least sufficient to produce the sought after biological effect. The vitamins and/or mineral admixture is

preferably combined with kelp, an acceptable and nutrient-rich feed grade
carrier.

Detailed Description Text - DETX (175):
Capsule-in-a-capsule vehicles appropriate for administration to livestock or
ratites are prepared by the method described hereinbefore. In this Example,
the vitamin and/or mineral admixture is in the inner capsule; and the outer
capsule contains the inner capsule and the probiotic. The vitamin and/or
mineral admixture is formulated to the specific animal, its age and for the
specific dietary purpose. The probiotic is selected from the list of non-spore
forms and/or live cell culture forms of Direct-Fed Microorganisms reviewed by
the Food and Drug Administration Center for Veterinary Medicine as in Example
24. By non-spore forms is meant that the probiotic culture does not exist
solely in the spore form. Where yeast is selected as a probiotic, only a live
cell yeast culture is used. The probiotic culture is present in a quantity at
least sufficient to produce the sought after biological effect. The vitamins
and/or mineral admixture is preferably combined with kelp, an acceptable and
nutrient-rich feed grade carrier.

Detailed Description Text - DETX (200):
Sample Y1 is prepared as disclosed in Example 8, using the
capsule-in-a-capsule vehicle with the inner capsule containing approximately 5
grams of live cell Saccharomyces cerevisiae culture, guaranteed at
10.times.10.sup.9 CFU/gram, (45.5% by weight of net contents), and the outer
capsule containing approximately 6 grams of the vitamin/mineral/kelp admixture
(54.5% by weight of net contents. Counts are conducted on the inner capsule
contents.

Detailed Description Text - DETX (202):
Sample Y3 is prepared as is disclosed in example 15, using the
capsule-in-a-capsule vehicle, with inner capsule containing approximately 5
grams of the vitamin/mineral/kelp admixture (38.5% by weight of net contents),
and outer capsule containing approximately 8 grams live cell Saccharomyces

cerevisiae culture, guaranteed at 10.times.10.sup.9 CFU/gram, (61.5% by weight
of net contents). Counts are conducted on the outer capsule probiotic contents.

Claims Text - CLTX (35):
29. A method for providing a dietary supplement to a food-producing animal,
comprising the steps of administering orally to said animal a double capsule
having an inner gelatin capsule and an outer gelatin capsule enclosing said
inner gelatin capsule, said double capsule including a nutritional supplement
therein, said double capsule further including viable gastrointestinal
microorganisms therein, said nutritional supplement partitioned from said
microorganisms; wherein said microorganisms are rendered non-viable when said
nutritional supplement and said microorganisms are stored in a bolus or single
capsule formulation; said microorganisms including one or more of
Lactobacillus acidophilus, Lactobacillus lactis, Lactobacillus casei,
Streptococcus faecium, Pediococcus cerevisiae, Bifidobacterium longum, live
cell yeast Saccharomyces cerevisiae, Aspergillus oryzae or Propionibacterium
freudenreichii; said nutritional supplement selected from the group consisting
of vitamins, minerals, and a combination of thereof, and wherein said vitamins
are selected from the group consisting of vitamin A, vitamin D, vitamin E,
vitamin B.sub.12, riboflavin, niacin, pantothenic acid, thiamine, choline,
folic acid, biotin, vitamin K, vitamin C, and a combination thereof, and
wherein said minerals are selected from the group consisting of cobalt, copper,
iron, manganese, zinc, selenium, and a combination thereof.